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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BERMAN, ALYSIA

ART UNIT PAPER NUMBER

1617

DATE MAILED: 08/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/978,027

Applicant(s)

MARTIN ET AL.

Examiner

Alysia Berman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Receipt is acknowledged of the information disclosure statement filed October 17, 2001 and the declaration and power of attorney filed February 19, 2002. Claims 1-13 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating signs of intrinsic or photoinduced cutaneous ageing, does not reasonably provide enablement for preventing signs of intrinsic or photoinduced cutaneous ageing. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification does not provide any data or examples to support prevention of signs of ageing. The presentation and prevention of signs of ageing are unpredictable. There are many signs of aging and many causes of signs of aging, not all of which are necessarily known. It would be very difficult to show that none of the signs of aging presented because of the use of the instant composition. The presentation and prevention of signs of aging depend on many variables including the susceptibility of the treated subject to showing signs of aging and other behaviors of the subject. It would be very difficult to document prevention of the signs of aging because it would have to be shown that the subject would necessarily

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have shown signs of aging without treatment and that signs of aging did not occur for the lifetime of the subject after treatment. It would take undue experimentation for one skilled in the art to use the composition to prevent signs of aging as instantly claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 7, 9 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7 and 9 are indefinite because it is unclear what Applicant intends to encompass by the instantly claimed derivatives. The derivatives are not exclusively defined by the claims or the specification. The metes and bounds of the claims cannot be determined.

Claim 11 is indefinite because it recites, "an inorganic pigment selected from the group consisting of **from** titanium dioxide." This phraseology makes the claim unclear.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,827,508 (508)

US '508 is directed to compositions with improved chemical, physical and photo stability that provide protection to the skin from ultraviolet radiation (abstract). The composition comprises a dibenzoylmethane sunscreen compound and surface-treated zinc oxide (abstract). For a benzophenone derivative as a UVA sunscreen see the dibenzoylmethane sunscreen disclosed as an ester formed from 2-hydroxy-4(2-hydroxyethoxy)benzophenone and 4-N,N(2-ethylhexyl)methylaminobenzoic at column 6, line 2-6 (claim 9). For oil-in-water emulsions see column 8, lines 57-60 (claim 5). Additional sunscreen agents that can be added to the composition include 2-ethylhexyl-p-methoxycinnamate, octyl salicylate, homomenthyl salicylate, 2-phenylbenzimidazole-5-sulfonic acid, 3-(4-methylbenzylidene)camphor, titanium dioxide, iron oxide and benzene-1,4-[bis(3-methylidenecamphormethylsulphonic)] acid (col. 9, line 45 to col. 10, line 7). Benzene-1,4-[bis(3-methylidenecamphormethylsulphonic)] acid is the same compound as claimed in instant claim 2. Other optional ingredients in the composition include retinal (col. 15, lines 7-11). Topical application to the skin is disclosed at column lines 15-18.

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US '508 does not disclose a composition comprising a compound of instant formula (I) in combination with retinol (claim 1) or other UVB (claims 6-8), UVA (claims 6, 9 and 10) and inorganic pigment (claim 11) sunscreen agents, from 0.01 to 0.15 wt.% retinol (claim 3), from 0.7-3 wt.% of the compound of formula (I) (claim 4), or a method of contacting retinol with a compound of instant formula (I) (claim 13).

US '508 teaches that the composition may contain all of the components instantly claimed. It is within the skill in the art to select optimal parameters in a composition in order to achieve a beneficial effect. *In re Boesch*, 205 USPQ 215 (CCPA 198). It would have been obvious for one skilled in the art to vary the proportions of components in a composition to arrive at the best compositions for the intended purpose. "It is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Only if the "results optimizing a variable" are "unexpectedly good" can a patent be obtained for the claimed critical range. *In re Antonie*, 559 F.2d 618, 620, 195 USPQ 6, 8 (CCPA 1977); see also *In re Dillon*, 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990) (in banc). It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). The idea of combining them flows logically from their having been individually taught in the prior art. *In re Crockett*, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960). Therefore, absent evidence of unexpected results the particular

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combination and concentration of components is not given patentable weight over the prior art.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of US '508 using any suitable combination of disclosed sunscreen agents and other active agents in optimal concentrations expecting to obtain a composition that provides protection to the skin from ultraviolet radiation that exhibits improved chemical, physical and photo stability.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,827,508 (508) as applied to claims 1-9 and 11-13 above, and further in view of US 6,015,548 (548).

US '508 teaches or suggests all the limitations of the claims as stated in the 35 U.S.C. 103(a) rejection above. It does not teach the UVA sunscreen agents of instant claim 10.

US '548 teaches that UVA sunscreen agents such as benzophenone-3 exhibit a synergistic effect of superior protection to the skin from ultraviolet radiation when combined with an antioxidant such as vitamin A (retinol). See the abstract and column 7, lines 57-59.

It would have been obvious to one of ordinary skill in the art at the time of the invention to add benzophenone-3 as taught in US '548 to the composition of US '508 expecting to obtain superior protection to the skin from ultraviolet radiation.

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Unexpected Results

It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, the data presented at page 10 of the instant specification does not show unexpected results of superior stability over the prior art.


Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-4638. The examiner can normally be reached Monday through Friday between 9:00 am and 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Russell Travers, can be reached on 703-308-4603. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 or 703-872-9307 for after-final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.


Alycia Berman
Patent Examiner
July 30, 2002


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